

R E M A R K S

Claims 1 to 3, 7, and 10 to 17 as set forth in Appendix II of this paper are now pending in this case. Claims 6, 8 and 9 have been canceled, Claims 1, 7 and 11 have been amended, and Claims 12 to 17 have been added, as indicated in the Listing of Claims set forth in Appendix I of this paper.

In addition to editorial changes in the wording of Claims 1, 7 and 11, applicants have replaced the expression "arylene, optionally substituted" by the phrase --optionally substituted arylene--, and the expression "where appropriate" by the term --optionally-- (Claims 1 and 7). Also, the last subsection of Claim 1 has been reworded to provide for antecedent basis of the phrase "the solution" in Claim 2, and to better bring out the fact that the initiator system is added in form of a solution of the initiator in the polyethylene glycol. Claim 7 has been revised accordingly. Claims 6, 8 and 9 have been canceled and rewritten as new Claims 12 to 17. No new matter has been added.

The Examiner has rejected Claims 1 and 3 under 35 U.S.C. §112, ¶2, in light of the wording "arylene, optionally substituted" and "where appropriate" in Claim 1. Favorable reconsideration of the Examiner's position and withdrawal of the respective rejection is respectfully solicited in light of the amendment addressed in the foregoing which removes the objectionable terminology.

The Examiner has rejected Claims 1 to 3 and 10 under 35 U.S.C. §103(a) as being unpatentable in light of the teaching in *GB 922,459* when taken in view of the disclosure of *Wu et al.* (US 5,338,814).

As further emphasized by the revised claim language, it is an essential requirement of applicants' process that a solution of a free-radical initiator in a liquid polyethylene glycol having a molecular weight of from 88 to 1000 is added as the free-radical initiator system for purposes of polymerizing the constituents (a), (b) and optionally (c).

The teaching of *GB 922,459* relates to a graft copolymerization of one or more vinyl esters on to one or more polyalkylene glycols in the presence of a free-radical forming initiator<sup>1</sup>). *GB 922,459* further provides that the polyalkylene glycols are particularly polyethylene

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1) For example page 1, indicated lines 31 to 40, of *GB 922,459*.

glycols having a molecular weight of 10000 up to several millions<sup>2)</sup>. The generic teaching of GB 922,459 does not provide information concerning the manner in which the free-radical initiator is added to the copolymerizable composition. In accordance with the representative examples provided in GB 922,459, the initiator is added to the polymerizable composition in substance.

The teaching of GB 922,459 not only fails to teach the utilization of liquid polyethylene glycols having a molecular weight of from 88 to 1000 but further differs from applicants' invention in several aspects. GB 922,459 fails to suggest or imply the utilization of a polyether corresponding to applicants' constituent (b). Additionally, GB 922,459 fails to suggest or imply to add the initiator to the polymerizable composition in form of a solution, and fails to suggest or imply the utilization of a liquid polyethylene glycol having a molecular weight of from 88 to 1000 as a solvent for the free-radical initiator.

The disclosure of Wu et al. relates to a free-radical solution polymerization of vinylpyrrolidine which is conducted in the presence of a polyethylene glycol having a molecular weight of about 300. According to Wu et al., the polyethylene glycol serves as a chain transfer reagent<sup>3)</sup> which provides for a narrow molecular weight distribution of the resulting polyvinylpyrrolidine. As such, the disclosure of Wu et al. is concerned with the preparation of a homopolymer rather than a graft copolymer.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success, and, finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Further, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and cannot be based on applicant's disclosure<sup>4)</sup>, and the level of skill in the art cannot be relied upon

2) For example page 2, indicated lines 68 to 71, of GB 922,459.

3) For example col. 2, indicated lines 40 to 48, of US 5,338,814.

4) In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (CAFC 1991)

to provide for a suggestion to combine references<sup>5</sup>). Accordingly, the mere fact that the prior art can be modified in some manner so as to arrive at a claimed invention does not support a conclusion of obviousness where the prior art fails to suggest the desirability of the specific modification which is required<sup>6</sup>).

In light of the differences between the preparation of graft copolymers on the one hand and (non-grafted) PVP homopolymers on the other hand, a person of ordinary skill would not have an inventive to modify the graft copolymerization taught by GB 922,459 by introducing parameters which are applied in the homopolymerization process of Wu et al. Furthermore, even when features of the homopolymerization process of Wu et al. are incorporated into the graft copolymerization process disclosed by GB 922,459, one cannot arrive at applicants' process since neither GB 922,459 nor Wu et al. suggest or imply the utilization of compounds within the definition of applicants' formula (I). The subject matter defined in applicants' claims therefore cannot be considered to be rendered prima facie obvious within the meaning of Section 103(a) by the teaching of GB 922,459 when taken in view of the disclosure of Wu et al. Favorable reconsideration of the Examiner's position and withdrawal of the rejection under Section 103(a) is respectfully solicited.

The Examiner has required election of, and restriction of the application to, one of the following groups of claims

- I) Claims 1 to 3 and 10, which relate to a process of making a particular graft copolymer;
- II) Claims 6 and 9 (*no longer pending*) which relate to a composition comprising the particular graft copolymer obtained by the process of Claim 1;
- III) Claims 7 and 11 which relate to the graft copolymer obtained by the process defined in Claim 1; and
- IV) Claim 8 (*no longer pending*) which relates to a composition comprising the particular graft copolymer obtained by the process of Claim 1;

contending that the claims define patentably distinct inventions.

5) Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 50 USPQ2d 1161, 1171 (CAFC 1999)

6) ie. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (CAFC 1984); see also, eg., Interconnect. Planning Corp. v. Feil, 774 F.2d 1132, 227 USPQ 543 (CAFC 1985)

With regard to groups I and III, the Examiner asserts that the process defined in applicants' Claim 1 can be used to make a product which materially differs from the product defined in Claim 7 because "the process can be used to make the starting materials of foamed substances".

It is not apparent how such starting materials could possibly be materially different from applicants' product which is defined in terms of a product-by-process and which recite the same limitations which characterize applicants' process. Since applicants' product necessarily has to be the product which is obtained by the process of Claim 1 any product resulting from the process of Claim 1 falls within the realm of Claim 7. The Examiner's argument is therefore not deemed to support a finding that Claims 1 and 7 define patentably distinct inventions.

Furthermore, MPEP §803 provides that two criteria have to be met for a requirement to restrict between patentably distinct inventions to be proper:

- (A) The inventions must be independent or distinct as claimed; and
- (B) There must be a serious burden on the examiner unless restriction is required.

As addressed in the foregoing, the Examiner has not met the burden to establish that applicants' process can be used to make another and materially different product. Accordingly, the first of the two criteria for a proper restriction requirement has not been met. Favorable reconsideration of the Examiner's position and withdrawal of the respective restriction requirement is therefore respectfully solicited.

New Claims 12 to 17 relate to a composition comprising the graft copolymer obtained by the process of Claim 1. The subject matter of the new claims and the subject matter defined in Claim 7 are, therefore, in a subcombination/combination relationship where the subcombination -in this case the graft copolymer defined in Claim 7- is essential to the combination. Accordingly, the consideration of Claims 12 to 17 along with Claims 1 and 7 does not require an additional search. Also, MPEP §806.05(c), subsection II, explains

*If there is no evidence that combination AB<sub>sp</sub> is patentable without the details of B<sub>sp</sub>, restriction should not be required. Where the relationship between the claims is such that the separately claimed subcombination B<sub>sp</sub> constitutes the essential distinguish-*

ing feature of the combination AB<sub>sp</sub> as claimed, the inventions are not distinct and a requirement for restriction must not be made, even though the subcombination has separate utility.

It is therefore deemed equitable that the subject matter of Claims 12 to 17 is examined along with the subject matter of Claims 1 to 3, 7, 10 and 11. Favorable action is respectfully solicited.

REQUEST FOR EXTENSION OF TIME:

It is respectfully requested that a two month extension of time be granted in this case. A check for the \$420.00 fee is attached.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit Account No. 11.0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

KEIL & WEINKAUF



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Encl.: THE LISTING OF CLAIMS (Appendix I)  
THE AMENDED CLAIMS (Appendix II)

HBK/BAS

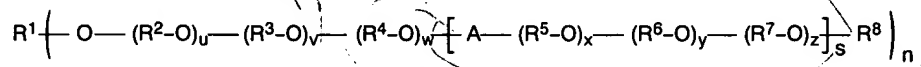
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# APPENDIX I:

## THE LISTING OF CLAIMS (version with markings, showing the changes made):

1. (currently amended) A process for preparing graft copolymers of polyvinyl esters ~~[by polymerization of]~~ which comprises polymerizing

- a) at least one vinyl ester of aliphatic C<sub>1</sub>-C<sub>24</sub>-carboxylic acids in the presence of
- b) polyethers which are solid at room temperature and have the general formula I



in which the variables have the following meaning, independently of one another:

R<sup>1</sup> hydrogen, C<sub>1</sub>-C<sub>24</sub>-alkyl, R<sup>9</sup>-C(=O)-, R<sup>9</sup>-NH-C(=O)-, polyalcohol residue;

R<sup>8</sup> hydrogen, C<sub>1</sub>-C<sub>24</sub>-alkyl, R<sup>9</sup>-C(=O)-, R<sup>9</sup>-NH-C(=O)-;

R<sup>2</sup> to R<sup>7</sup> -(CH<sub>2</sub>)<sub>2</sub>-, -(CH<sub>2</sub>)<sub>3</sub>-, -(CH<sub>2</sub>)<sub>4</sub>-, -CH<sub>2</sub>-CH(CH<sub>3</sub>)-, -CH<sub>2</sub>-CH(CH<sub>2</sub>-CH<sub>3</sub>)-, -CH<sub>2</sub>-CHOR<sup>10</sup>-CH<sub>2</sub>-;

R<sup>9</sup> C<sub>1</sub>-C<sub>24</sub>-alkyl;

R<sup>10</sup> hydrogen, C<sub>1</sub>-C<sub>24</sub>-alkyl, R<sup>9</sup>-C(=O)-;

A -C(=O)-O-, -C(=O)-B-C(=O)-O-, -C(=O)-NH-B-NH-C(=O)-O-;

B -(CH<sub>2</sub>)<sub>t</sub>-, optionally substituted arylene[~~optionally substituted~~];

n 1 to 8;

s 0 to 500;

t 1 to 12;

u 1 to 5000;

v 0 to 5000;

w 0 to 5000;

x 1 to 5000;

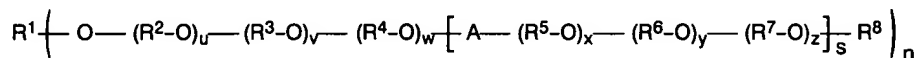
y 0 to 5000;

z 0 to 5000

- c) and~~[where appropriate]~~ optionally at least one other monomer ~~[using]~~ by adding a free-radical initiator system, wherein the free-radical initiator system is a solution of a free-radical initiator in a liquid polyethylene glycol having a molecular

weight between 88 and 1000 [~~is used as solvent for the free-radical initiator~~].

2. (previously presented) A process as claimed in claim 1, wherein the solution of the free-radical initiator is added continuously throughout the polymerization reaction time.
3. (previously presented) A process as claimed in claim 1, wherein liquid polyethylene glycol is used as solvent for the free-radical initiator at room temperature.
4. (canceled)
5. (canceled)
6. (canceled)
7. (currently amended) [~~Graft copolymers~~] A graft copolymer of polyvinyl esters [which are the products of the] obtained by a process [of polymerization of] which comprises polymerizing
  - a) at least one vinyl ester of aliphatic C<sub>1</sub>-C<sub>24</sub>-carboxylic acids in the presence of
  - b) polyethers which are solid at room temperature and have the general formula I



in which the variables have the following meaning, independently of one another:

R<sup>1</sup> hydrogen, C<sub>1</sub>-C<sub>24</sub>-alkyl, R<sup>9</sup>-C(=O)-, R<sup>9</sup>-NH-C(=O)-, polyalcohol residue;

R<sup>8</sup> hydrogen, C<sub>1</sub>-C<sub>24</sub>-alkyl, R<sup>9</sup>-C(=O)-, R<sup>9</sup>-NH-C(=O)-;

R<sup>2</sup> to R<sup>7</sup> -(CH<sub>2</sub>)<sub>2</sub>-, -(CH<sub>2</sub>)<sub>3</sub>-, -(CH<sub>2</sub>)<sub>4</sub>-, -CH<sub>2</sub>-CH(CH<sub>3</sub>)-, -CH<sub>2</sub>-CH(CH<sub>2</sub>-CH<sub>3</sub>)-, -CH<sub>2</sub>-CHOR<sup>10</sup>-CH<sub>2</sub>-;

R<sup>9</sup> C<sub>1</sub>-C<sub>24</sub>-alkyl;

R<sup>10</sup> hydrogen, C<sub>1</sub>-C<sub>24</sub>-alkyl, R<sup>9</sup>-C(=O)-;

A -C(=O)-O-, -C(=O)-B-C(=O)-O-, -C(=O)-NH-B-NH-C(=O)-O-;

B -(CH<sub>2</sub>)<sub>t</sub>-, optionally substituted arylene[~~optionally substituted~~];

n 1 to 8;

s 0 to 500;

t 1 to 12;

u 1 to 5000;  
v 0 to 5000;  
w 0 to 5000;  
x 1 to 5000;  
y 0 to 5000;  
z 0 to 5000

c) and~~[, where appropriate,]~~ optionally at least one other monomer ~~[using]~~ by adding a free-radical initiator system, wherein the free-radical initiator system is a solution of a free-radical initiator in a liquid polyethylene glycol having a molecular weight between 88 and 1000 ~~[is used as solvent for the free-radical initiator]~~.

8. (canceled)

9. (canceled)

10. (previously presented) The process of claim 1, wherein the molecular weight of the liquid polyethylene glycol is between 100 and 600.

11. (currently amended) The graft copolymer defined in claim 7, which is ~~[produced]~~ obtained using liquid polyethylene glycol having a molecular weight between 100 and 600 as solvent for the free-radical initiator.

E1  
cont  
12. (new) A composition comprising conventional excipients and at least one of the polymers obtained by the process of claim 1.

13. (new) The composition defined in claim 12, which comprises the polymer(s) in an amount effective for film-forming, binding, wetting or solubilizing.

14. (new) The composition defined in claim 13, which is adapted as a coating agent, a binder or a film-forming excipient for pharmaceutical dosage forms.

15. (new) The composition defined in claim 12 which further comprises an active ingredient which is effective for cosmetic, hygienic, dermatological or pharmaceutical application.

16. (new) The composition defined in claim 15 which is in form of a cosmetic, hygienic, dermatological or pharmaceutical dosage form.



17. (new) The composition defined in claim 15 which is in form of a cosmetic, hygienic or pharmaceutical preparation.

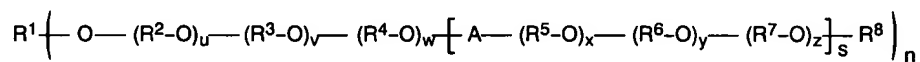
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## A P P E N D I X II:

THE AMENDED CLAIMS (clean version of all claims):

1. (currently amended) A process for preparing graft copolymers of polyvinyl esters which comprises polymerizing
- at least one vinyl ester of aliphatic C<sub>1</sub>-C<sub>24</sub>-carboxylic acids in the presence of
  - polyethers which are solid at room temperature and have the general formula I



in which the variables have the following meaning, independently of one another:

R<sup>1</sup> hydrogen, C<sub>1</sub>-C<sub>24</sub>-alkyl, R<sup>9</sup>-C(=O)-, R<sup>9</sup>-NH-C(=O)-, polyalcohol residue;

R<sup>8</sup> hydrogen, C<sub>1</sub>-C<sub>24</sub>-alkyl, R<sup>9</sup>-C(=O)-, R<sup>9</sup>-NH-C(=O)-;

R<sup>2</sup> to R<sup>7</sup> -(CH<sub>2</sub>)<sub>2</sub>-, -(CH<sub>2</sub>)<sub>3</sub>-, -(CH<sub>2</sub>)<sub>4</sub>-, -CH<sub>2</sub>-CH(CH<sub>3</sub>)-, -CH<sub>2</sub>-CH(CH<sub>2</sub>-CH<sub>3</sub>)-, -CH<sub>2</sub>-CHOR<sup>10</sup>-CH<sub>2</sub>-;

R<sup>9</sup> C<sub>1</sub>-C<sub>24</sub>-alkyl;

R<sup>10</sup> hydrogen, C<sub>1</sub>-C<sub>24</sub>-alkyl, R<sup>9</sup>-C(=O)-;

A -C(=O)-O-, -C(=O)-B-C(=O)-O-, -C(=O)-NH-B-NH-C(=O)-O-;

B -(CH<sub>2</sub>)<sub>t</sub>-, optionally substituted arylene;

n 1 to 8;

s 0 to 500;

t 1 to 12;

u 1 to 5000;

v 0 to 5000;

w 0 to 5000;

x 1 to 5000;

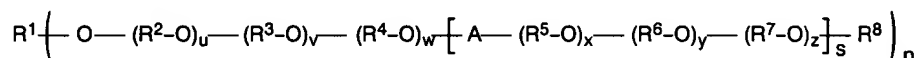
y 0 to 5000;

z 0 to 5000

- and optionally at least one other monomer

by adding a free-radical initiator system, wherein the free-radical initiator system is a solution of a free-radical initiator in a liquid polyethylene glycol having a molecular weight between 88 and 1000.

2. (previously presented) A process as claimed in claim 1, wherein the solution of the free-radical initiator is added continuously throughout the polymerization reaction time.
3. (previously presented) A process as claimed in claim 1, wherein liquid polyethylene glycol is used as solvent for the free-radical initiator at room temperature.
4. (canceled)
5. (canceled)
6. (canceled)
7. (currently amended) A graft copolymer of polyvinyl esters obtained by a process which comprises polymerizing
  - a) at least one vinyl ester of aliphatic C<sub>1</sub>-C<sub>24</sub>-carboxylic acids in the presence of
  - b) polyethers which are solid at room temperature and have the general formula I



in which the variables have the following meaning, independently of one another:

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R<sup>8</sup> hydrogen, C<sub>1</sub>-C<sub>24</sub>-alkyl, R<sup>9</sup>-C(=O)-, R<sup>9</sup>-NH-C(=O)-;

R<sup>2</sup> to R<sup>7</sup> -(CH<sub>2</sub>)<sub>2</sub>-, -(CH<sub>2</sub>)<sub>3</sub>-, -(CH<sub>2</sub>)<sub>4</sub>-, -CH<sub>2</sub>-CH(CH<sub>3</sub>)-, -CH<sub>2</sub>-CH(CH<sub>2</sub>-CH<sub>3</sub>)-, -CH<sub>2</sub>-CHOR<sup>10</sup>-CH<sub>2</sub>-;

R<sup>9</sup> C<sub>1</sub>-C<sub>24</sub>-alkyl;

R<sup>10</sup> hydrogen, C<sub>1</sub>-C<sub>24</sub>-alkyl, R<sup>9</sup>-C(=O)-;

A -C(=O)-O-, -C(=O)-B-C(=O)-O-, -C(=O)-NH-B-NH-C(=O)-O-;

B -(CH<sub>2</sub>)<sub>t</sub>-, optionally substituted arylene;

n 1 to 8;

s 0 to 500;

t 1 to 12;

u 1 to 5000;

v 0 to 5000;

w 0 to 5000;

x 1 to 5000;

y 0 to 5000;

z 0 to 5000

c) and optionally at least one other monomer

by adding a free-radical initiator system, wherein the free-radical initiator system is a solution of a free-radical initiator in a liquid polyethylene glycol having a molecular weight between 88 and 1000.

8. (canceled)

9. (canceled)

10. (previously presented) The process of claim 1, wherein the molecular weight of the liquid polyethylene glycol is between 100 and 600.

11. (currently amended) The graft copolymer defined in claim 7, which is obtained using liquid polyethylene glycol having a molecular weight between 100 and 600 as solvent for the free-radical initiator.

12. (new) A composition comprising conventional excipients and at least one of the polymers obtained by the process of claim 1.

13. (new) The composition defined in claim 12, which comprises the polymer(s) in an amount effective for film-forming, binding, wetting or solubilizing.

14. (new) The composition defined in claim 13, which is adapted as a coating agent, a binder or a film-forming excipient for pharmaceutical dosage forms.

15. (new) The composition defined in claim 12 which further comprises an active ingredient which is effective for cosmetic, hygienic, dermatological or pharmaceutical application.

16. (new) The composition defined in claim 15 which is in form of a cosmetic, hygienic, dermatological or pharmaceutical dosage form.

17. (new) The composition defined in claim 15 which is in form of a cosmetic, hygienic or pharmaceutical preparation.